# **Program Announcement**

# Department of Defense (DOD) Congressionally Directed Medical Research Programs

# **Prostate Cancer Research Program (PCRP)**

# **Health Disparity Research Award**

# Funding Opportunity Number: W81XWH-09-PCRP-HDRA

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## I. FUNDING OPPORTUNITY DESCRIPTION

# A. Program Objectives

The Prostate Cancer Research Program (PCRP) was established in fiscal year 1997 (FY97) to promote innovative research focused on eradicating prostate cancer. Appropriations for the PCRP from FY97 through FY08 totaled \$890 million (M). The FY09 appropriation is \$80M.

The overall goal of the FY09 PCRP is to find and fund innovative, high-impact research relevant to the prevention, detection, diagnosis, and/or treatment of human prostate cancer. Specifically, the PCRP seeks to:

- Support innovative research by individual investigators in multiple disciplines;
- Sponsor multidisciplinary team science to bring together diverse expertise and approaches that will accelerate the conquering of prostate cancer;
- Fund translational research to promote the bench-to-bedside-to-bench transition between basic and clinical science;
- Foster the next generation of prostate cancer investigators through mentored research and training;
- Promote research into prostate cancer health disparities, including, but not limited to, race and ethnicity, socioeconomic status, access to health care, insurance status, age, geography, and cultural beliefs; and
- Promote research on patient survivorship, life extension, and quality of life.

## FY09 PCRP Focus Areas (New)

**Imaging:** Development of new imaging technology for the detection, prognosis, and treatment of prostate cancer.

**Biomarkers:** Discovery and validation of biomarkers for the detection, prognosis, and treatment of prostate cancer, including the determination of therapeutic response.

**Therapy:** Identification of new targets, pathways, and therapeutic modalities or molecules for the treatment of prostate cancer.

**Genetics:** Understanding the genetics and epigenetics responsible for prostate cancer susceptibility, disease progression, and treatment outcomes.

**Tumor Biology:** Understanding the etiology of prostate cancer, including heterogeneity and microenvironment as it relates to initiation, progression, and prognosis.

**Survivorship:** Studies on the impacts of treatment, nutrition, metabolism, and exercise on the well-being of prostate cancer patients and their families.

Applications for the PCRP Health Disparity Research Award must address one or more of the focus areas and have a direct relevance to prostate cancer prevention, detection, diagnosis, and/or treatment. Applications will be rated on their responsiveness to the FY09 PCRP focus areas.

# **B.** Award Description

The PCRP Health Disparity Research Award mechanism was introduced in FY01. Since then, 142 applications have been received and 39 have been recommended for funding.

The PCRP seeks applications from all areas of basic, preclinical, behavioral, and epidemiological research, that are responsive to one or more of the FY09 PCRP focus areas. *NEW FOR FY09:* PIs wishing to apply for funding for population-based studies should consider submitting an application for the Population-based Idea Development Award.

The Health Disparity Research Award reflects the PCRP's commitment to resolving disparities in prostate cancer incidence, morbidity, and mortality by funding health disparity-focused projects by investigators at multiple points in their careers:

- **Transitioning Investigators:** Mentored investigators preparing for their first independent faculty position and their own research programs.
- Early-Career Investigators: Independent investigators in the early stages of their careers.
- **Established Investigators:** Independent investigators at or above the level of Assistant Professor or equivalent.

# Appropriate disparity areas include, but are not limited to:

- Race and ethnicity,
- Socioeconomic status,
- Access to health care,
- Insurance status,
- Age,
- · Geography, and
- Cultural beliefs.

PIs who do not have either experience in prostate cancer research or a connection to, or effectiveness in working with, an affected population or community are strongly encouraged to include a collaborator (or collaborators) with the appropriate prostate cancer or health disparity research experience. Such experience may include:

- Being a member of the affected population or community with a demonstrated commitment to the affected population or community;
- Having experience working with the affected population or community; or
- Having interactions with or an active membership in organizations such as the Urban League, National Medical Association, National Alliance for Hispanic Health, American Indian Health Care Association, National Rural Health Association, Patient Advocate Foundation National African American Outreach Program, or Prostate Health Education Network (PHEN).

The proposal must explicitly state how the proposed research is related to a health disparity area in prostate cancer.

**NOTE:** Clinical trials are not allowed under this mechanism. Refer to the Application Instructions and General Information, Appendix 6, for helpful information about distinguishing clinical trials and clinical research.

Specific information for each category of Health Disparity Research Award appears below. Each PI may apply in only one category.

	Transitioning	Early-Career	Established
	Investigator	Investigator	Investigator
Research Experience	Minimum 2 years post-doctoral research	Within 3 years of having received first independent faculty appointment	Greater than 3 years as independent faculty
Other personnel required?	Yes – Mentor	Yes – Collaborator	No
Most important aspects	<ul><li>(1) PI</li><li>(2) Mentor</li><li>(3) Career Development Program and Environment</li></ul>	<ul><li>(1) Personnel</li><li>(2) Impact</li><li>(3) Research Strategy and Feasibility</li></ul>	<ul><li>(1) Innovation</li><li>(2) Impact</li><li>(3) Research Strategy and Feasibility</li></ul>

Further details on each award can be found below:

1. Transitioning Investigator: These mentored awards are designed to support investigators who, at the time of submission, have completed a minimum of 2 years of postdoctoral research and are preparing for their first independent faculty position (or equivalent). PIs will be expected to obtain their first independent faculty position within 2 years of award initiation.

The first independent position is defined as the Assistant Professor level or an equivalent faculty position (e.g., Assistant Member, Laboratory Head, Principal Investigator, etc.), at which the candidate is expected to establish his or her own research program, prepare applications for additional research funding, and act as a PI on such independent research projects.

These awards will provide investigators committed to prostate cancer health disparity research the opportunity to acquire, in the late stages of their postdoctoral research and as they begin their first independent faculty position, the data and experience needed to be competitive for research funding later in their career.

It is the responsibility of the Principal Investigator (PI) to clearly and explicitly articulate how the project addresses the following important aspects of the Transitioning Investigator Award:

- **a. PI's qualifications:** The PI must demonstrate strong qualifications for and a commitment to an independent career in prostate cancer health disparity research.
- **b. Mentor:** Submission to this award mechanism as a Transitioning Investigator requires a designated *mentor*, appropriate to the proposal, who has experience in prostate cancer health disparity research as demonstrated by a record of funding and publications. The selected mentor should be well-qualified to significantly contribute to the development of the PI toward a career in prostate cancer health disparity research.
- c. Research and career development environment: The PI must describe his or her research project as well as his or her career goals in the body of the proposal. Proposals should either extend the PI's ongoing research related to prostate cancer health disparity or broaden the scope of his or her research to include work relevant to health disparities, under the guidance of a designated mentor with expertise in prostate cancer health disparity research. To encourage submissions from PIs early in their careers, proposals are not required to have preliminary data. Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team.
- **d. Responsiveness to focus areas:** The relevance of the research problem to one or more of the FY09 PCRP focus areas.
- **2. Early-Career Investigator:** These awards are designed to foster independent PIs, in the early stages of their careers, (see <u>Eligibility</u>, below) who have innovative, high-impact ideas or new technologies applicable to prostate cancer health disparities. Funds are intended to provide 50% protected time for research.

It is the responsibility of the Principal Investigator (PI) to clearly and explicitly articulate how the project addresses the following important aspects of the Early-Career Investigator Award:

- **a. Personnel:** The PI and collaborator are emphasized in this award. The PI's record of accomplishment will be evaluated regarding his or her potential for contributing to the prostate cancer health disparity research field. The PI and collaborator together will be emphasized in peer review to determine whether their combined background and prostate cancer-related expertise demonstrate the ability to accomplish the proposed work.
- **b. Impact:** Research that has high impact will, if successful, significantly contribute to the goal of reducing prostate cancer health disparity.

- c. Preliminary Data: To encourage submissions from PIs early in their careers, proposals are not required to have preliminary data. Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team. Although groundbreaking research often involves a degree of risk due to unforeseen difficulties or results, these proposals should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature.
- **d. Innovation:** Innovative research may represent a new paradigm, challenge existing paradigms, or look at existing problems from new perspectives. This may include high-risk approaches to prostate cancer research provided that there is potential for significant impact. Research that is an incremental advance upon published data is not considered innovative, and will not be considered for funding under this award mechanism.
- **e. Responsiveness to focus areas:** The relevance of the research problem to one or more of the FY09 PCRP focus areas.
- **3. Established Investigator:** These awards support innovative studies of prostate cancer health disparities from independent investigators at the Assistant Professor level or above (see <u>Eligibility</u>, below).

It is the responsibility of the Principal Investigator (PI) to clearly and explicitly articulate how the project addresses the following important aspects of the Established Investigator Award:

- **a. Innovation:** Innovative research may represent a new paradigm, challenge existing paradigms, or look at existing problems from new perspectives. This may include high-risk approaches to prostate cancer research provided that there is potential for significant impact. Research that is an incremental advance upon published data is not considered innovative and will not be considered for funding under this mechanism.
- **b. Impact:** Research that has high impact will, if successful, significantly contribute to the goal of reducing prostate cancer health disparity.
- **c. Responsiveness to focus areas:** The relevance of the research problem to one or more of the FY09 PCRP focus areas.
- d. Preliminary Data: Submission of preliminary data relevant to prostate cancer and the proposed project is encouraged but not required. Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team. Although groundbreaking research often involves a degree of risk due to unforeseen difficulties or results, these proposals should be based on a sound scientific rationale that is established through logical reasoning and/or critical review and analysis of the literature.

# C. Eligibility

Eligibility criteria for each category are listed below. *Each PI may apply for only one category of award:* 

# 1. Transitioning Investigator

- Must have a *designated* mentor with experience in prostate cancer health disparity research:
- Must hold a Ph.D. and/or an M.D. degree, or equivalent doctoral degree;
- By application submission deadline, must have completed a minimum of 2 years of postdoctoral research.

# **2.** Early-Career Investigator: Independent investigators who, at application submission deadline:

- Are within 3 years of having received first independent faculty position (or equivalent);
- Have the freedom to pursue individual aims without formal mentorship; and
- Can provide evidence of institutional support, such as start-up funds by the institution, use of a technician, space, facilities, and resources.

PIs working within a laboratory team are eligible to apply for this award provided that they can demonstrate that they are independent investigators according to the criteria above.

- **3. Established Investigator:** The PI, at application submission deadline, must be:
  - An independent investigator with access to facilities appropriate for health disparity research, and
  - Greater than 3 years beyond first appointment as independent faculty.

Refer to the Application Instructions and General Information, Appendix 1, for general eligibility information.

## D. Funding

- The maximum period of performance is 3 years.
- The maximum allowable direct cost funding for the entire period of performance is listed below.
- The applicant may request the entire maximum direct cost amount for a project that may be less than the maximum 3-year period of performance.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum direct cost. In addition to the direct costs, indirect costs may be proposed in accordance with your institution's negotiated rate agreement.

	Transitioning	Early-Career	Established
	Investigator	Investigator	Investigator
Maximum Funding (Direct Costs for the entire period of performance)	\$225,000	\$225,000	\$450,000

Within the guidelines provided in the Application Instructions and General Information, funds can cover:

- Salary
- Research supplies
- Equipment
- Clinical research costs (Clinical trials are not supported)
- Travel between collaborating institutions
- Travel to scientific/technical meetings

In addition, funding must be requested for the PI to travel to *one* PCRP IMPaCT (Innovative Minds in Prostate Cancer Today) Meeting.

The CDMRP expects to allot approximately \$5M of the \$80M FY09 PCRP appropriation to fund approximately nine Health Disparity Research Award applications, depending on the quality and number received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent on the availability of Federal funds for this program.

# E. Award Administration

Changes in PI are not allowed for the Transitioning Investigator and Early-Career Investigator categories of this award, except under extreme circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer, provided that the intent of the award mechanism is met.

For Transitioning Investigator Awards, the submitting institution must agree to relinquish the award when the PI obtains an independent faculty position, or equivalent, at another institution so that it can be transferred to the new institution.

Refer to the Application Instructions and General Information, Appendix 5, for general award administration information on changes in award personnel or institution.

## II. TIMELINE FOR SUBMISSION AND REVIEW

Proposal submission is a two-step process consisting of (1) pre-application submission and (2) application submission. *Pre-application submission is a required first step*.

Pre-application Submission Deadline: April 29, 2009, 5:00 p.m. Eastern Time

Confidential Letters of Recommendation: May 20, 2009, 5:00 p.m. Eastern Time

Application Submission Deadline: May 20, 2009, 11:59 p.m. Eastern Time

Scientific Peer Review: July/August 2009

Programmatic Review: October 2009

Awards will be made approximately 4 to 6 months after receiving a funding notification letter, but no later than September 30, 2010.

## III. SUBMISSION PROCESS

Proposal submission is a two-step process consisting of (1) a pre-application submission through the <u>CDMRP eReceipt system</u> (<u>https://cdmrp.org/</u>), and (2) an application submission through <u>Grants.gov</u> (<u>http://www.grants.gov/</u>).

PIs and organizations identified in the application submitted through Grants.gov should be the same as those identified in the pre-application. If there is a change in PI or organization after submission of the pre-application, the PI must contact the eReceipt help desk at: <a href="help@cdmrp.org">help@cdmrp.org</a> or 301-682-5507.

Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs is discouraged. The Government reserves the right to reject duplicative applications.

# A. Step 1 – Pre-Application Components and Submission

**Pre-application submission is the required first step.** The pre-application consists of the components discussed below. All pre-application components must be submitted electronically through the <a href="CDMRP eReceipt system">CDMRP eReceipt system</a> by **5:00 p.m. Eastern time on the deadline date**. In addition to award-specific information provided below, refer to the Application Instructions and General Information for detailed information on pre-application components and submission.

- Proposal Information
- Proposal Contacts
- Collaborators and Conflicts of Interest (COI)
- Letter of Intent (LOI) Narrative
- List of Individuals Providing Confidential Letters of Recommendation (Transitioning Investigator PIs only)

# B. Step 2 – Application Components and Submission

Applications will not be accepted unless the pre-application process is completed by the pre-application deadline. Applications must be submitted electronically by the Authorized Organizational Representative (AOR) through Grants.gov (www.grants.gov).

Each application submission must include the completed application package of forms and attachments identified in <a href="www.grants.gov">www.grants.gov</a> for the US Army Medical Research Acquisition Activity (USAMRAA) Program Announcement/Funding Opportunity. In addition to the specific instructions below, please refer to the Application Instructions and General Information for detailed requirements of each component.

The package includes:

# 1. SF-424 (R&R) Application for Federal Assistance Form

## 2. Attachments Form

- Attachment 1: Project Narrative (10-page limit)
  - Transitioning Investigator

Describe the proposed project in detail using the outline below. The inclusion of preliminary data relevant to prostate cancer and the proposed project is encouraged but not required. Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team.

**PI's Career Goals:** Describe the PI's career goals in prostate cancer health disparity research and how the proposed research and career development experience will promote an independent career in this area. Discuss the PI's career plans after the completion of this award.

**Research Project:** Describe the proposed project, including background, hypothesis/rationale/purpose, objectives, and methods. Discuss the relevance of this research to prostate cancer health disparities. *This award may not be used to conduct clinical trials.* 

Career Development Program: Describe the career development program, which may include conferences, seminars, journal clubs, teaching responsibilities, and/or clinical responsibilities. The PI is expected to obtain his or her first independent faculty position within 2 years of award initiation. Describe the mentor's background and experience in prostate cancer health disparity research and discuss how the mentor will assist the PI in developing his or her career as an independent prostate cancer health disparity researcher. Explain how the career development program is supported by the environment; this should include a description of ongoing prostate cancer health disparity research at the institution. Include information on collaborations with other investigators.

**Integration of Career Development and Research:** Describe how the career development and research programs are integrated and how they will contribute to preparing the PI for an independent career in prostate cancer health disparity research.

**Connection to Community:** Explicitly demonstrate how the proposed research is related to a health disparity area within an affected population or community.

# Early-Career Investigator

Describe the proposed project in detail using the outline below. The inclusion of preliminary data relevant to prostate cancer and the proposed project is encouraged but not required. Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team.

**Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application.

**Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.

**Specific Aims:** Concisely explain the project's specific aims. If this application is part of a larger study, present only tasks that the DOD award would fund.

**Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Explain how the PI will have access to the appropriate population. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. *This award may not be used to conduct clinical trials.* 

**Collaborator:** Name the required collaborator and describe how he or she will support the PI and project. The PI and collaborator together will be emphasized in peer review to determine whether their combined background and prostate cancer-related expertise demonstrate the ability to accomplish the proposed work.

**Connection to Community:** Explicitly demonstrate how the proposed research is related to a health disparity area within an affected population or community.

# Established Investigator

Describe the proposed project in detail using the outline below. The inclusion of preliminary data relevant to prostate cancer and the proposed project is encouraged but not required. Any preliminary data provided should be from the laboratory of the PI or member(s) of the collaborating team.

**Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application.

**Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.

**Specific Aims:** Concisely explain the project's specific aims. If this application is part of a larger study, present only tasks that the DOD award would fund.

**Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Explain how the PI will have access to the appropriate population. Address potential problem areas and present alternative methods and approaches. If human subjects or human biological samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples. *This award may not be used to conduct clinical trials*.

**Connection to Community:** Explicitly demonstrate how the proposed research is related to a health disparity area within an affected population or community.

- Attachment 2: Supporting Documentation
  - References Cited
  - Acronyms and Symbol Definitions
  - Facilities & Other Resources
  - Description of Existing Equipment
  - Publications and/or Patent Abstracts (five-document limit)
  - Letters of Institutional Support

Provide a letter(s) of institutional support, signed by the Department Chair or appropriate institutional official, that reflects the laboratory space, equipment, and other resources available for this project. The letter(s) should indicate the level of institutional commitment to fostering the PI's career, as reflected by (1) the extent to which the PI will be relieved of clinical or other responsibilities to have additional time for research, (2) the provision of adequate laboratory facilities and equipment, and (3) opportunities for critical professional interaction with senior colleagues with established research careers. For Early-Career Investigator PIs this letter must demonstrate a commitment to allow at least 50% protected time for research.

 Letter(s) of support from population- or community-based organizations (if applicable).

In cases where the PI is affiliated with a designated population- or community-based organization (e.g., the Urban League, National Medical Association, National Alliance for Hispanic Health, American Indian Health Care Association, National Rural Health Association, Patient Advocate Foundation National African American Outreach Program, or Prostate Health Education Network [PHEN]), a letter of support from each organization is encouraged. Such letter(s) of support should explain the nature of the PI's relationship to the organization, the involvement of the PI with the affected population or community, the importance of the project within the affected population or community, any long-term application of the project to the affected population or community, and the PI's commitment to the affected population or community and health disparity.

- Letters of Collaboration
  - **Required** (*for Early-Career Investigator PIs only*): Provide a signed letter (2-page limit recommended) from the required collaborator(s) that describes how he or she will support the PI and the project.
  - If applicable: Provide a signed letter from each additional collaborating individual or institution that will demonstrate that the PI has the resources necessary for the proposed work. Established Investigator PIs who do not have experience in prostate cancer research or a connection to, or effectiveness in working with, an affected population or community are strongly encouraged to include a collaborator (or collaborators) with the appropriate prostate cancer or health disparity research experience.
- Documentation of Rights to Project (for Transitioning Investigator PIs only, if applicable).
  - For Transitioning Investigator PIs who are completing postdoctoral fellowships (or equivalent) at the time of submission and plan to continue their current projects during the tenure of this award, provide a letter from the laboratory director (or equivalent) affirming that the PI has full rights to the project and may continue it at either the same or another institution after beginning the faculty appointment.
- o Intellectual and Material Property Plan (if applicable)
- Attachment 3: Technical Abstract
- Attachment 4: Public Abstract
- Attachment 5: Statement of Work (SOW)
- Attachment 6: Detailed Budget and Justification
- Attachment 7: Impact Statement
  - State explicitly how the proposed work will, if successful, have an impact on human prostate cancer and how the expected results of the project will contribute to the goals of conquering prostate cancer and advancing research on the prevention, detection, diagnosis, or treatment of the disease.
- Attachment 8: Innovation Statement (for Early-Career and Established PIs only)
   Summarize how the proposed work is innovative. Investigating the next logical step or incremental advancement on published data is not considered innovative.
  - **Although not all-inclusive**, the following examples are ways in which the proposed work may be innovative and are intended to help PIs frame the innovative features:
  - Study concept: Investigation of a novel idea and/or research question.
  - Research method or technology: Use of novel research methods or new technologies, including technology development, to address a research question.
  - Novel method or technology: Development of a novel method or technology for preventing, detecting, diagnosing, or treatment.

- Existing methods or technologies: Application or adaptation of existing methods or technologies for novel research or clinical purposes, or for research or clinical purposes that differ fundamentally from those originally intended.
- Attachment 9: Focus Area Statement
  - Describe how the proposed research addresses one or more of the FY09 PCRP focus areas.
- Attachment 10: Statement of Eligibility (Transitioning Investigator and Early-Career Investigator PIs only).
- Attachment 11: Federal Agency Financial Plan (if applicable)
- Attachments 12-15: Subaward Detailed Budget and Justification (if applicable)

# 3. Research & Related Senior/Key Person Profile (Expanded Form)

- PI Biographical Sketch (four-page limit)
- PI Current/Pending Support
- Key Personnel Biographical Sketches (four-page limit each)
   For the Transitioning Investigator Award, a biographical sketch of the PI's mentor is required.
- Key Personnel Current/Pending Support
   For the Transitioning Investigator Award, Current/Pending Support for the PI's mentor is required.
- 4. Research & Related Project/Performance Site Location(s) Form

Confidential Letters of Recommendation (required for Transitioning Investigator PIs only; two-page limit per letter recommended): In addition to the completed Grants.gov application package of forms and attachments, Transitioning Investigator proposals also require the submission of three confidential letters of recommendation by the individuals designated during the pre-application process. The PI should monitor whether the letters have been received; however, the PI is not permitted or able to view these letters. If confidential letters of recommendation cannot be submitted by the individuals named in the pre-application, the PI must contact the CDMRP eReceipt help desk at help@cdmrp.org or 301-682-5507.

The confidential letters should include the following:

- A confidential letter of recommendation from the mentor, describing his or her commitment to the PI's career development and mentorship in prostate cancer health disparity research. The mentor should address the following in his or her confidential letter of recommendation:
  - o The PI's potential to become an independent prostate cancer health disparity researcher within the next 2 years.
  - The mentor's proposed interactions with the PI, to include continuation into the PI's first faculty appointment.

- o The research and career development environment, including ongoing prostate cancer health disparity research, and how this environment will promote the development of the PI as an independent prostate cancer health disparity researcher.
- Research being performed with the mentor's guidance and how this research is relevant to prostate cancer health disparities.
- o How the mentor will assist the PI in developing an independent career in prostate cancer health disparity research.
- The mentor's history of supporting the development of investigators at the early stages of their careers.
- The resources available to adequately support the PI's project (specific details on existing support should be covered in the Existing/Pending Support section).
- Two additional confidential letters of recommendation.

Refer to the Application Instructions and General Information for additional information regarding submission of the confidential letters of recommendation.

## IV. INFORMATION FOR APPLICATION REVIEW

# A. Application Review and Selection Overview

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a scientific peer review of applications against established criteria for determining scientific merit. The second tier is a programmatic review that compares submissions to each other and recommends proposals for funding based on scientific merit, the overall goals of the program, and the specific intent of the award mechanism. Additional information about the two-tier review process used by the CDMRP may be found at <a href="http://cdmrp.army.mil/fundingprocess">http://cdmrp.army.mil/fundingprocess</a>

The peer review and programmatic review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Each tier of review requires panelists to sign a non-disclosure statement attesting that application and evaluation information will not be disclosed outside the panel. Violations of the non-disclosure statement can result in the dissolving of a panel(s) and other corrective actions. Institutional personnel and PIs are prohibited from contacting persons involved in the application review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the institution's application. Violations by panelists or PIs that compromise the confidentiality of the peer review and programmatic review processes may also result in suspension or debarment of their employing institutions from Federal awards. Furthermore, it is a crime for Federal officials to disclose confidential information of one party to another third party (Title 18 United States Code 1905).

The Government reserves the right to review all applications based on one or more of the required attachments or supporting documentation (e.g., Innovation Statement or Impact Statement).

## B. Review Criteria

## 1. Peer Review

**a.** Transitioning Investigator: All Transitioning Investigator applications will be evaluated according to the following criteria. Of these, Principal Investigator, Mentor, and Career Development Program and Environment are equally the most important, with the remaining criteria listed in decreasing order of importance.

# Principal Investigator

- How the PI's achievements (as reflected by academic performance, awards, honors, and previous findings) indicate a potential for success in prostate cancer health disparity research.
- How confidential letters of recommendation from the mentor and others support the PI's potential to obtain an independent faculty position within the next 2 years and develop a productive career in prostate cancer health disparity research.
- To what degree the levels of effort are appropriate for successful conduct of the proposed work.
- To what extent the PI demonstrates the potential to become a successful independent prostate cancer health disparity researcher.
- How the PI's stated career goals demonstrate a commitment to pursuing a career as a prostate cancer health disparity researcher.
- The extent to which the PI demonstrates a connection to, or effectiveness in working with, the affected populations or communities.
- Whether the PI meets the appropriate eligibility requirements.

#### Mentor

- How the mentor's achievements in preparing investigators for careers in health disparity research indicate the potential for successful mentorship for the PI.
- How the mentor's prostate cancer health disparity research experience and program, as demonstrated by a record of funding and publications, and level of effort are appropriate for the proposed project.
- Whether the quality of the application suggests that the mentor provided appropriate guidance.
- The extent to which the mentor demonstrates a connection to or effectiveness in working with the affected populations or communities.

# • Career Development Program and Environment

• How well the PI has outlined an individualized career development program that augments his or her expertise.

- How well the career development program will prepare the PI for obtaining an independent faculty position, or equivalent, and foster an independent career in prostate cancer health disparity research.
- How well the career development program addresses an issue related to prostate cancer health disparities.
- How the scientific environment is appropriate for the proposed career development activities, including critical professional interaction with established senior research colleagues.
- How the quality and extent of other institutional support are appropriate.

# • Research Strategy and Feasibility

- How well the scientific rationale supports the research project and its feasibility as demonstrated by a critical review and analysis of the literature, prostate cancer-relevant preliminary data, and/or logical reasoning.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
- Whether the research requirements are supported adequately by the scientific environment, necessary resources, and any collaborative arrangements proposed.
- How well the research project will allow the PI to develop the expertise needed to advance an independent career in prostate cancer health disparity research.
- How well the PI acknowledges potential problems and addresses alternative approaches.

## • Responsiveness to Focus Area(s)

 How well the proposed research project responds to one or more the FY09 PCRP focus areas toward the goal of advancing prostate cancer research.

## Impact

- How well the proposed research addresses an issue of health disparity in prostate cancer in the affected population or community.
- How the project, if successful, could make an original and significant contribution to the goal of decreasing prostate cancer health disparity.

The following criteria will not be individually scored, but may impact the overall evaluation of the application:

# Budget

 How the budget is appropriate for the proposed research and within the limitations of the award mechanism.

# Application Presentation

How the writing and components of the application influenced the review.

**b.** Early-Career Investigator: All **Early-Career Investigator** applications will be evaluated according to the following criteria, which are listed in decreasing order of importance.

## Personnel

- Whether the PI meets the eligibility requirements.
- How the PI's record of accomplishment demonstrates his or her potential for contributing to the field of prostate cancer health disparity research and completing the proposed work.
- The extent to which the research team demonstrates a connection to or effectiveness in working with the affected populations or communities.
- How the PI and collaborator's background and prostate cancer-related expertise are appropriate with respect to their ability to perform the proposed work.
- To what degree the levels of effort are appropriate for successful conduct of the proposed work.

# • Impact

- How well the proposed research addresses an issue of health disparity in prostate cancer in the affected population or community.
- The extent to which the project, if successful, could make an original and significant contribution to the goal of decreasing prostate cancer health disparity.

# • Research Strategy and Feasibility

- How well the scientific rationale supports the research project and its feasibility as demonstrated by a critical review and analysis of the literature, prostate cancer-relevant preliminary data, and/or logical reasoning.
- How well the hypothesis or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
- How well the PI acknowledges potential problems and addresses alternative approaches.

# • Responsiveness to Focus Area(s)

How well the proposed research project responds to one or more the FY09
 PCRP focus areas toward the goal of advancing prostate cancer research.

## Innovation

- How well the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
- How the proposed research represents more than an incremental advance upon published data.

The following criteria will not be individually scored, but may impact the overall evaluation of the application:

#### Environment

- Whether there is a clear institutional commitment to allow 50% protected time for research.
- How the scientific environment is appropriate for the proposed research.
- How the research requirements are supported adequately by the availability of and accessibility to facilities and resources (including collaborative arrangements).
- How the quality and extent of other institutional support are appropriate.

# Budget

• How the budget is appropriate for the proposed research and within the limitations of the award mechanism.

# • Application Presentation

- How the writing and components of the application influenced the review.
- **c. Established Investigator:** All Established Investigator applications will be evaluated according to the following criteria, which are listed in decreasing order of importance.

#### Innovation

- How well the research proposes new paradigms or challenges existing paradigms in one or more of the following ways: concept or question, research methods or technologies, adaptations of existing methods or technologies, or other ways.
- How the proposed research represents more than an incremental advance upon published data.

## Impact

- How well the proposed research addresses an issue of health disparity in prostate cancer in the affected population or community.
- The extent to which the project, if successful, could make an original and significant contribution to the goal of decreasing prostate cancer health disparity.

# Research Strategy and Feasibility

- How the scientific rationale supports the research project and its feasibility as demonstrated by a critical review and analysis of the literature, prostate cancerrelevant preliminary data, and/or logical reasoning.
- How well the hypothesis or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.

 How well the PI acknowledges potential problems and addresses alternative approaches.

# Responsiveness to Focus Area(s)

How well the proposed research project responds to one or more the FY09
 PCRP focus areas toward the goal of advancing prostate cancer research.

## Personnel

- The extent to which the research team demonstrates a connection to or effectiveness in working with the affected populations or communities.
- How the research team's background and prostate cancer-related expertise are appropriate with respect to their ability to perform the proposed work.
- To what degree the levels of effort are appropriate for successful conduct of the proposed work.
- Whether the PI meets the eligibility requirements.

The following criteria will not be individually scored, but may impact the overall evaluation of the application:

#### Environment

- How the scientific environment is appropriate for the proposed research.
- How the research requirements are supported adequately by the availability and accessibility to facilities and resources (including collaborative arrangements).
- How the quality and extent of other institutional support are appropriate.

## Budget

• How the budget is appropriate for the proposed research and within the limitations of the award mechanism.

# • Application Presentation

- How the writing and components of the application influenced the review.
- **2. Programmatic Review:** The following criteria are used by programmatic reviewers to make funding recommendations that maintain the program's broad portfolio:
  - Adherence to the intent of the award mechanism
  - Programmatic relevance
  - Ratings and evaluations of the peer reviewers
  - Relative innovation (Early Career and Established Investigators only), impact, and responsiveness to FY09 PCRP focus areas
  - Program portfolio balance

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the program will be identified by Integration Panel (IP) members and recommended for funding to the Commanding General, USAMRMC.

## V. ADMINISTRATIVE ACTIONS

After receipt of applications from Grants.gov, the following administrative actions may occur.

# A. Rejection

The following will result in administrative rejection of the application:

- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

## **B.** Modifications

- Pages exceeding the specified limits will be removed for all documents other than the Project Narrative.
- Documents not requested will be removed.
- *NEW for FY09:* Following the application deadline, you may be contacted by CDMRP via email with a request to provide certain missing supporting documents (excluding those listed directly above in Section A, Rejection). The missing documents must be provided within 48 hours of the date and time the email was sent. Otherwise the application will be reviewed without the missing documents.

## C. Withdrawal

The following may result in administrative withdrawal of the application:

- FY09 IP member(s) is found to be involved in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting document. A list of the FY09 IP members may be found at <a href="http://cdmrp.army.mil/pcrp/panel09">http://cdmrp.army.mil/pcrp/panel09</a>
- Submission of the same research project to different award mechanisms within the same program or to other CDMRP programs.
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate scientific peer and programmatic review.
- Direct costs as shown on the detailed budget form exceed the maximum allowed by the award mechanism.
- Inclusion of URLs, with the exception of links to published references.

## D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be requested to provide the findings of the investigation to the USAMRAA Contracting/Grants Officer for a determination of the final disposition of the application.

## VI. CONTACT INFORMATION

**A.** Program Announcement/Funding Opportunity, application format, or required documentation: To view all funding opportunities offered by the CDMRP, perform a Grants.gov basic search using the CFDA Number 12.420. Submit questions as early as possible. Response times will vary depending upon the volume of inquiries. Every effort will be made to answer questions within 5 working days.

Phone: 301-619-7079 Fax: 301-619-7792

Email: cdmrp.pa@amedd.army.mil

**B. eReceipt system:** Questions related to pre-application components through the CDMRP eReceipt system should be directed to the eReceipt help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern time.

Phone: 301-682-5507 Website: <a href="https://cdmrp.org">https://cdmrp.org</a> Email: help@cdmrp.org

**C. Grants.gov contacts:** Questions related to application submission through the <u>Grants.gov</u> (<a href="http://www.grants.gov/">http://www.grants.gov/</a>) portal should be directed to the Grants.gov help desk. Deadlines for application submission are 11:59 p.m. Eastern time on the deadline date. Please note that the CDMRP help desk is unable to answer questions about Grants.gov submissions.

Phone: 800-518-4726, Monday through Friday, 7:00 a.m. to 9:00 p.m. Eastern time

Email: <a href="mailto:support@grants.gov">support@grants.gov</a>

Grants.gov will notify PIs of changes made to this Program Announcement/Funding Opportunity and/or Application Package ONLY if the PI subscribes to the mailing list by clicking on the "send me change notification emails" link on the Opportunity Synopsis page for this announcement. If the PI does not subscribe and the Application Package is updated or changed, the original version of the Application Package may not be accepted.